



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Henry A. Waxman
Chairman
Committee on Oversight and Government Reform
House of Representatives
Washington, D.C. 20515-6143

DEC 21 2007

Dear Mr. Chairman:

Thank you for your letter dated November 30, 2007, regarding an October 2007 internal draft guidance for industry about the good reprint practices for the distribution of medical journal articles and medical or scientific reference publications on unapproved new uses of approved drugs and approved or cleared medical devices. In your letter, you expressed concerns about the internal draft guidance. Also, you requested that the Food and Drug Administration (FDA or the Agency) provide information and documents related to the internal draft guidance. As we have discussed with your staff, FDA is scheduling a briefing with your office on the distribution of reprints to provide background information and previous statutory guidelines related to this issue.

FDA develops guidance documents consistent with Title 21, *United States Code* (U.S.C.) 371(h) and the implementing regulations at Title 21, *Code of Federal Regulations* (CFR) 10.115. The document in question is a draft of a draft guidance, which, assuming it completes internal review, FDA would issue for public comment, not for implementation. FDA would welcome comments from you and any other Member of Congress on that document at that time.

Materials requested in your letter contain deliberative pre-decisional information and their disclosure could have detrimental implications for the process by which guidance documents are generated and vetted. See 21 CFR 10.115. The Agency has a confidentiality interest in materials that reflect its ongoing internal deliberative process. It is critically important that experts within FDA be able to thoroughly evaluate and candidly discuss available information related to guidance development and other matters. The Agency's ability to protect and promote the public health depends on its ability to conduct objective analyses and to base its decisions on sound science. We believe it is crucial to the Agency's proper execution of its public health mission to protect the ongoing deliberative decision-making process. Therefore, we are not providing materials that reflect these ongoing deliberations.

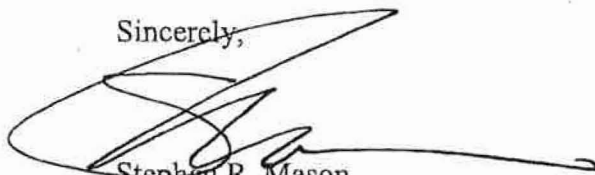
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In response to request No. 3 of your letter, although we are not aware of any reported Federal court decisions since February 2000 that expressly prohibit or restrict FDA's authority to consider dissemination of journal articles, there have been a number of significant commercial free speech cases. See, e.g. Thompson v. Western States Medical Center, 535 U.S. 357 (2002); Borgner v. Florida Board of Dentistry, 537 U.S. 1080 (2002); Nike, Inc. v. Kasky, 537 U.S. 1099 (2003); cert. dismissed as improvidently granted, Nike, Inc. v. Kasky, 539 U.S. 654 (2003); and Whitaker v. Thompson, 353 F.3d 947 (D.C. Cir. 2004).

Additionally, your staff has brought our attention to an article that mentions an April 2007 meeting with parties from outside the government about distribution of reprints. In response to a Freedom of Information Act request from the reporter of that article, FDA provided a copy of the minutes of that meeting. Although those minutes do not reflect a discussion of the draft guidance that is the subject of your letter, we nevertheless have produced them to your office.

We are committed to continuing to work diligently with you to respond to the oversight needs of the Committee. Please do not hesitate to contact us if you have any questions.

Sincerely,



Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosure

cc: The Honorable Tom Davis
Ranking Member
Committee on Oversight and Government Reform
House of Representatives
Washington, D.C. 20515-6143

MEMORANDUM OF MEETING

April 13, 2007
Washington, DC

FDA:

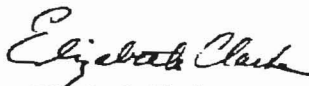
Andrew C. von Eschenbach, M.D., Randy Lutter, Sheldon Bradshaw, Jeff Shuren, Jarilyn Dupont, Jeff Senger, Jane Axelrad, Mike Landa, Linda Kahan, Dan McChesney, David Horowitz, Kristen Smith, Elizabeth Clarke,

Sidley Austin: Paul Kalb, Dan Troy, Coleen Klasmeier, Alan Bennett, Joan McPhee

Subject: Peer-review journal articles

Meeting Summary

After introductions, Mr. Troy explained that Sidley Austin represents a number of companies that are concerned about dissemination of peer-reviewed journal articles. FDAMA allowed the practice of distributing this information, but the provision has now sunset. Sidley Austin spoke about their perceptions as well as the effect and consequences of the sunset provision. Mr. Kalb provided an overview of the problems companies face. He also expressed concerns about Federal prosecutors pursuing distributors of this information for criminal misconduct. There is confusion about the rules, possibly an FDA guidance could clarify the rules.



Elizabeth Clarke
Policy Analyst
FDA Executive Secretariat